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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,486	10/15/2001	Yi-Jyun Lin	06618-343002	5129

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FISH & RICHARDSON, PC  
4350 LA JOLLA VILLAGE DRIVE  
SUITE 500  
SAN DIEGO, CA 92122

EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 06/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/978,486

Examiner

Janet L Andres

Applicant(s)

LIN ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18 and 20 is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-17, 19, 21, 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other \_\_\_\_\_

### **RESPONSE TO AMENDMENT**

1. Applicant's amendment filed 12 April 2002 is acknowledged. Claims 1-4 and 6-22 are pending in this application. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

#### ***Claim Rejections Withdrawn***

2. The rejection of claims 1-8 as indefinite in the recitation of "binding", "binding reagent", and "mth" is withdrawn in response to Applicant's amendment.

#### ***Claim Rejections/Objections Maintained/New Grounds of Rejection***

3. The objection to the specification is maintained. Applicant's amendment updating the priority information and inserting a sequence identifier on p. 79 is acknowledged. However, there are sequences in figure 4 that lack sequence identifiers.

The specification is additionally objected to because the amendment filed 12 April 2002 contains new matter. There is no support for "at least 15 contiguous amino acids" as recited in new claim 21.

4. Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as containing new matter. This claim recites fragments of "at least 15" contiguous amino acids. There is no support for "at least 15" in the specification.

5. The rejection of claims 4-8 under 35 U.S.C. 112, first paragraph, as lacking written

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Applicant argues that the structure of the mth polypeptide is shown, along with hydrophilic and hydrophobic regions. Applicant further argues that the effects of failure to express mth are shown. Applicant has amended the claims to recite variants of SEQ ID NO: 2.

Applicant's arguments have been fully considered but have not been found to be persuasive. The amended claims recite proteins of 85% homology to SEQ ID NO: 2, as well as sequences identified by hybridization, with the limitation that these sequences function as mth polypeptides. However, while Applicant has presented certain structural characteristics of SEQ ID NO: 2, there is no particular activity associated with the molecule. What is known are effects resulting from its absence. There is no measurable function associated with SEQ ID NO: 2, and Applicant has taught no regions that are otherwise definitive; the hydrophobicity plot does not distinguish it from any other 7 transmembrane region protein. Thus, one of skill in the art would not be able to determine which variants had the characteristics of the mth polypeptide, because one of skill would not know what those characteristics were and would have no way of determining whether they had been altered. Internal variants would also create different epitopes which Applicant has not described. Thus, antibodies created against such variants would not necessarily be antibodies against molecules with the same properties of SEQ ID NO:2. Since there is no way to identify such molecules, there is also no way to identify antibodies against them. Thus one of skill in the art would not conclude that Applicant was in possession of variants of SEQ ID NO:2 with the defining characteristics of SEQ ID NO:2, and thus of antibodies against such variants.

REMARKS: FIGURE 1: Schematic of the structure of the mth polypeptide. FIGURE 2: A schematic of an antibody against SEQ ID NO: 2.

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polypeptide comprising an antigenic fragment. The antibody could thus be against sequences not present in SEQ ID NO: 2. As set forth above, Applicant has not defined either the characteristics of such variants, nor has Applicant defined epitopes that might be present in such variants. Thus one of skill in the art would not conclude that Applicant was in possession of either sequences comprising antigenic fragments or antibodies against them. Changing section c) in each claim to read "consisting of an antigenic fragment" would obviate this rejection, because the antibody would then of necessity be generated against a known fragment of SEQ ID NO:2.

7. The rejection of claims 4-8 under 35 U.S.C. 112, first paragraph, as lacking enablement commensurate with the scope of the claims is maintained and newly applied to claims 1-3 and new claims 15, 16, and 21.

Applicant's amendment is not sufficient to overcome this rejection. For the reasons set forth above, Applicant has not described the characteristics of SEQ ID NO: 2 so that one of skill in the art could identify other molecules that had the same characteristics. There is no particular activity associated with SEQ ID NO: 2 that would allow one of skill in the art to identify other molecules with the same activity, and there are no other characteristics presented that are definitive of SEQ ID NO: 2. Since internal variations could also generate different epitopes that Applicant has not described, one of skill in the art could not predict that antibodies against such variants would have the same characteristics as antibodies against SEQ ID NO: 2. Since there is no way to determine which antibodies would have the desired properties, one of skill in the art could thus not make and use Applicant's invention as broadly claimed.

Applicant's amendment is not sufficient to overcome this rejection. For the reasons set forth above, the

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antibodies against the molecules of section c) could be against sequences not defined or predictable based on Applicant's disclosure, one of skill in the art could not predictably make them.

9. Claims 1-4, 6-8, 15, 15, and 21 are newly rejected under 35 U.S.C. 112, second paragraph, as indefinite in the recitation of "stringent conditions" or "highly stringent conditions" and of "functional activity". "Stringent" and "highly stringent" are not defined in the specification. What is presented on p. 28 are examples only. "Functional activity" is also not defined. What is set forth in the specification on p. 22 are examples of changes that result from lack of expression of the protein. As stated above, there is no actual activity of the polypeptide disclosed.

10. Claims 9-17 and 22 are newly rejected under 35 U.S.C. 112, second paragraph, as indefinite. It is unclear which polypeptides are referred to in the preamble. Rewriting claims 9, 17, and 22 to read ...an antibody which selectively binds to

a) a polypeptide ...

b) a polypeptide...

c) a polypeptide...

or

d) a polypeptide...

would clarify the nature of the claimed antibody.

Claim 17 is additionally indefinite in the recitation of the final polypeptide. Amending

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NO: 2" would clarify the claim so that one of skill in the art would be able to determine the characteristics of the claimed antibodies.

11. Claim 19 is drawn to an antibody against a polypeptide located in a hydrophilic domain. No such polypeptides are described. Hydrophilic domains are, however, described, and one of skill in the art would know what was intended by an antibody that "selectively binds the hydrophilic domain".

CLAIMS 18 AND 20 ARE ALLOWED. CLAIMS 1-4, 6-17, 19, 21, AND 22 ARE REJECTED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov](mailto:yvonne.eyler@uspto.gov).

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that

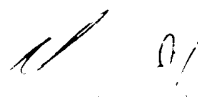
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set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.

June 19, 2002

  
VALERIE E. LEE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600